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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,448	04/14/2004	Mitchell Weiss	CHOP.0189US	6608

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EXAMINER	
HAMA, JOANNE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,448	WEISS ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Application was filed April 14, 2004 and claims priority to U.S. Provisional Applications 60/462,771, filed April 14, 2003 and 60/477,991, filed June 12, 2003.

Claims 1-38 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a mouse harboring a homozygous null mutation in the Alpha hemoglobin Stability Protein (AHSP) gene, classified in class 800, subclass 18.

II. Claims 5-8, drawn to a mouse harboring a heterozygous null mutation in the Alpha hemoglobin Stability Protein gene, classified in class 800, subclass 18.

III. Claims 9-13 drawn to a method for screening for therapeutic agents which affect AHSP, using the mice of claim 1, classified in class 536, subclass 23.1, or class 514, subclass 1+.

IV. Claims 14-16, drawn to a method of diagnosing an AHSP-related disorder in a test subject, classified in class 536, subclass 23.1 or class 530, subclass 350+.

V. Claim 17, drawn to a method of screening for compounds which modulate the activity of an AHSP polypeptide, the method comprising contacting at least one test compound with the AHSP polypeptide in a reaction medium, classified in class 530, subclass 350+.

VI. Claim 18, drawn to a compound identified by the method of claim 11 or 17 wherein the compound is a fragment of AHSP, or a small molecule which mimics AHSP activity, classified in class 530, subclass 300+, or class 514, subclass 1+.

VII. Claims 19-22, drawn to a method of treating or ameliorating symptoms of an AHSP-related disorder, comprising overexpressing an AHSP encoding nucleic acid molecule in the cells or body fluid of a patient having said disorder, classified in class 536, subclass 23.1.

VIII. Claims 23-26, drawn to a method for producing anti-AHSP antibodies and an anti-AHSP antibody preparation, classified in class 530, subclass 350+.

IX. Claim 27, drawn to a kit comprising one or more molecules for detecting AHSP expression, said molecules being selected from the group consisting of nucleic acid molecules having sequence corresponding to a portion of an AHSP nucleic acid sequence and antibodies which specifically bind to a portion of the AHSP protein, classified in class 536, subclass 23.1, and class 530, subclass 300+.

X. Claim 28, drawn to a transgenic mouse characterized by overexpression of an AHSP gene, classified in class 800, subclass 13.

XI. Claim 29, drawn to a mouse having a homozygous null mutation in the AHSP gene and a heterozygous null mutation in beta major and minor globulin genes, classified in class 800, subclass 18.

XII. Claims 30, 31, drawn to a method for assessing the activity of compounds useful for the treatment and/or prevention of an AHSP-related disorder using the mice in claim 29, classified in class 536, subclass 23.1 or class 514, subclass 1+.

XIII. Claim 32, drawn to a compound identified by the method of claim 30, classified in class 536, subclass 23.1 or class 514, subclass 1+.

XIV. Claim 33, drawn to a method of treating or ameliorating symptoms of an AHSP-related disorder, comprising administering the compound of claim 32 to the cells or body fluid of a patient having said disorder, classified in class 536, subclass 23.1, or class 514, subclass 1+.

XV. Claim 34 drawn to a having a homozygous null mutation in the AHSP gene and a homozygous null mutation in at least one alpha globulin gene, classified in class 800, subclass 18.

XVI. Claims 35, 36, drawn to a method for assessing the activity of compounds useful in the treatment and/or prevention of an AHSP-related disorder using the mice in claim 34, classified in class 536, subclass 23.1 or class 514, subclass 1+.

XVII. Claim 37, drawn to a compound identified by the method of claim 35, classified in class 536, subclass 23.1 or class 514, subclass 1+.

XVIII. Claim 38, drawn to a method of treating or ameliorating symptoms of an AHSP-related disorder comprising administering the compound of claim

37 to the cells or body fluid of a patient having said disorder, classified in class 536, subclass 23.1, or class 514, subclass 1+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, X, XI, XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, while each of these Inventions are mice with genetic modifications, each mouse has a unique genetic modification and thus have different phenotypes and will be used in different ways from each other. One mouse model does not depend on another to function.

Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Invention III is a method for screening therapeutic agents using a mouse model. Invention VI is a compound isolated from a screen using a mouse model. Invention VI can be used in a different method: a method of treating a patient.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Invention V is to an *in vitro* method of screening compounds. Invention VI is to a compound identified from the screen. The method of identifying one compound, using the *in vitro* method, can be used to isolate other compounds.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention III are to an *in vivo* method of using a mouse model to identify a compound. Invention V is to an *in vitro* method of identifying a compound. Invention III does not depend on Invention V to function and vice versa.

Inventions I/III, XI/XII, and XV/XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Inventions I, XI, XV are mice with genetic modifications. Inventions III, XII, XVI are methods of using the mice to assess activity of a compound. The mice can also be used in a method of treating a disease.

Inventions I/VI, XI/XIII, and XV/XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions I, XI, XV are mice with genetic modifications. Inventions VI, XIII, XVII are compounds isolated from a method for assessing the activity of a compound useful for treatment and/or prevention of an AHSP-related disorder. Inventions I, XI, XV do not depend on Inventions VI, XIII, XVII to function and vice versa.

Inventions I/VII, XI/XIV, and XV/XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Inventions I, XI, XV are mice with genetic modifications. Inventions XVII, XIV, XVIII are to methods of treating the mice. The mice can also be used in a method to assess the activity of a compound.

Inventions III/VI, XII/XIII, and XVI/XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Inventions III, XII, XVI are to methods of assessing the activity of a compound.

Inventions VI, XIII, XVII are to a compound. Inventions VI, XIII, XVII can be use in another method: a method of treating a patient.

Inventions III/VII, XII/XIV, XVI/XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions III, XII, XVI are to a method of assessing activity of a compound. Inventions VII, XIV, XVIII are to a method of treating a patient. Inventions III, XII, XVI do not depend on Inventions VII, XIV, XVIII to function and vice versa.

Inventions VI/VII, XIII/XIV, XVII/XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Inventions VI, XIII, XVII are to a compound. Inventions VII, XIV, XVIII are to methods of treating a patient using these compounds. The compounds can be used in another method: a method of assessing the activity of a compound.

Inventions I/III/VI/VII, XI/XII/XIII/XIV, AND XV/XVI/XVII/XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, while the different Inventions are to a mouse model, a method of assessing activity of a compound, the

compound identified from a method assessing its activity, and a method of treating a patient, each set of these Inventions are based on mice with different genetic modifications and thus, different phenotypes. The use of these mice in a method to identify compounds and in a method to treat a disease will be different from each other. Further, the compounds identified using these mice will be different from each other.

Inventions I/IV/VII/IX, XIII/XIV/XV/XVI, and XV/XVI/XVII/XVIII and II/X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions I/IV/VII/IX, XIII/XIV/XV/XVI, and XV/XVI/XVII/XVIII are to a mouse model, a method of assessing activity of a compound, the compound identified from a method assessing its activity, and a method of treating a patient. Inventions II/X are mouse models. Inventions I, II, X, XI, and XV are each mice with different genetic modifications and thus different phenotypes. Each mouse model is unique. Inventions I/IV/VII/IX, XIII/XIV/XV/XVI, and XV/XVI/XVII/XVIII are to methods of using the mice to isolate a compound and to treating a disease. Further the Inventions are to a compound. None of these methods or the compounds depends on the mice of Inventions II/X to function and vice versa.

Inventions I/IV/VII/IX, XIII/XIV/XV/XVI, and XV/XVI/XVII/XVIII and V/VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as

capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions I/IV/VII/IX, XIII/XIV/XV/XVI, and XV/XVI/XVII/XVIII are to a mouse model, a method of assessing activity of a compound, the compound identified from a method assessing its activity, and a method of treating a patient. These are *in vivo* methods and the compound isolated from the method of assessing the activity of a compound from a mouse was carried out via an *in vivo* method. Inventions V/VI are to an *in vitro* method of identifying a compound and to the compound itself. Inventions I/IV/VII/IX, XIII/XIV/XV/XVI, and XV/XVI/XVII/XVIII do not depend on Inventions V/VI to function and vice versa.

Inventions II/X and V/VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions II/X are to two mice with different genetic modifications. Inventions V/VII are to an *in vitro* method of isolating a compound and to the compound isolated from this method. Inventions II/X do not depend on Inventions V/VII to function and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification,

recognized divergent subject matter, and the search for one group is not required for the other, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JH